DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

91600d

VIA FEDERAL EXPRESS

**WARNING LETTER**

**FLA-01-73**

July 26, 2001

Henry Alonso, President
Holiday Seafood, Incorporated
589 Island Drive
Tarpon Springs, Florida 34691

Dear Mr. Alonso:

We completed an inspection of your seafood processing plant, located at the above address, on May 29, 2001 and found that you continue to have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh refrigerated scombrotoxin forming fish products such as mahi-mahi and tuna to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a HACCP plan that lists appropriate critical control points, to comply with 21 CFR 123.6(c)(2). However, your current HACCP plan for fresh refrigerated scombrotoxin forming fish species does not list the critical control points of receiving, raw material and finished product storage to control the food safety hazard of histamines in fish species such as mahi-mahi and tuna.

For each critical control point in your HACCP plan, you must have the following: critical limit(s), monitoring procedures for the critical limits, the frequency that you will conduct the monitoring, verification procedures and the frequency for verification. You must also have a record keeping system for these items. In addition, if you choose to do so, you may list a pre-determined corrective action plan in your HACCP plan.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice (GMP) regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans, monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District